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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,044	12/07/2005	Walid Nagib Aboul-Hosn	17040.4a.1	6603

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WORKMAN NYDEGGER
60 EAST SOUTH TEMPLE
1000 EAGLE GATE TOWER
SALT LAKE CITY, UT 84111

EXAMINER	
FLORY, CHRISTOPHER A	
ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,044	ABOUL-HOSN, WALID NAGIB	
	Examiner	Art Unit	
	CHRISTOPHER A. FLORY	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 26 September 2007 have been fully considered but they are not persuasive. Claims 1-4, 8 and 12 stand rejected under 35 U.S.C. 102(b) as being anticipated by Izraelev (US Patent 5,685700, hereinafter Izraelev'700). Claims 1-10 and 12-15 stand rejected under 35 U.S.C. 102(e) as being anticipated by Schulte Eistrup et al. (US Patent 6,752,602, hereinafter Eistrup'602).

2. In response to applicant's argument that neither Izraelev'700 nor Eistrup'602 discloses that the device an be implanted using a minimally invasive procedure (page 6, paragraph 5), a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Furthermore, it is considered that both the Izraelev'700 and Eistrup'602 can inherently be placed using minimally invasive procedures.

3. Regarding Applicant's argument that Izraelev'700 and Eistrup'602 teach the opposite taper of the instant claim 16 (page 7, paragraph 1), it is noted that the language of claim 16 does not specify a direction of tapering wherein one end must specifically be narrower than the other, merely that the ends are in a tapered relationship. As admitted by Applicant, both Izraelev'700 and Eistrup'602 disclose inlets that taper.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claims 1-4, 8, 12 and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Izraelev (US Patent 5,685700, hereinafter Izraelev'700).

Regarding claims 1-3 and 16, Izraelev'700 discloses a blood pump for percutaneous introduction into a patient (TITLE) comprising a pump housing (Fig. 2, housing 11) having at least two blood inlets disposed on opposing ends of said pump housing (ABSTRACT; column 2, lines 13-16; Fig. 2 inlets 16 and 17); at least one blood outlet pump disposed between the blood inlets (ABSTRACT; Fig. 3, outlets 18 and 19); a rotor chamber extending between the inlets and outlets (Fig. 2, chamber 12); and a rotor operable to draw blood into the inlets and direct blood to said outlets (ABSTRACT; Fig. 2, rotor 20); wherein the pump housing is considered inherently capable of insertion using a minimally invasive procedure.

Further regarding claim 16, Izraelev'700 shows each of the blood inlets tapering from a first end toward a second end, the second end communicating with the rotor chamber (Fig. 3, inlets 16 and 17 are clearly tapered).

Regarding claims 4 and 17, Izraelev'700 discloses an outflow cannula coupled to said blood outlet that is integral with the housing (Fig. 3, outlets 18 & 19), wherein a cannula is understood to be a hollow metal tube for withdrawal or insertion of a fluid.

Regarding claims 8 and 12, Izraelev'700 discloses cooperating magnets to position said rotor within said pump housing and a control system to control said motor (abstract; column 1, lines 22-25; column 4, lines 37-56).

Regarding claim 18, the outflow cannula 18 is considered to comprise a discharge chamber and can be seen in figure 3 to be generally parallel to rotor chamber 32.

6. Claims 1-10 and 12-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Schulte Eistrup et al. (US Patent 6,752,602, hereinafter Eistrup'602).

Regarding claims 1-3 and 16, Eistrup'602 discloses a blood pump for percutaneous introduction into a patient (TITLE) comprising a pump housing (Fig. 1, housing 10) having at least two blood inlets disposed on opposing ends of said pump housing (ABSTRACT; Fig. 1, inlets 14 and 16); at least one blood outlet pump disposed between the blood inlets (ABSTRACT; Fig. 1, outlet 18); a rotor chamber extending between the inlets and outlets (Fig. 1, chamber 12); and a rotor operable to draw blood into the inlets and direct blood to said outlets (ABSTRACT; Fig. 1, rotor 20); wherein the

pump housing is considered inherently capable of insertion using a minimally invasive procedure.

Further regarding claim 16, Eistrup'602 shows each of the blood inlets tapering from a first end toward a second end, the second end communicating with the rotor chamber. In figure 1, elements 14 and 16 can be considered part of the inlets and are clearly tapered as they approach the rotor chamber. Additionally, Figure 6 shows a tapered inlet generally seen at element 38.

Regarding claims 4 and 17, Eistrup'602 discloses an outflow cannula coupled to said blood outlet (column 8, line 67). Figures 2 and 3 show outflow cannula 18 to be integral with the housing.

Regarding claim 18, Eistrup'602 is considered to disclose a discharge chamber in that the outflow cannula can reasonably be defined as a discharge chamber, and can be seen in Figure 3 to run generally parallel to the rotor chamber centered about element 24.

Regarding claim 9, Eistrup'602 discloses thrust bearings (abstract; column 3, lines 10-13; Fig. 1, bearing pair 34).

Regarding claims 8, 10 and 12, Eistrup'602 discloses cooperating magnets to position said rotor within said pump housing and a control system to control said motor (column 3, lines 35-42; column 4, lines 45-47; Fig. 1, rotor magnets 28).

Regarding claims 13-15, Eistrup'602 discloses a rechargeable, subcutaneous battery (column 9, lines 5-10).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Izraelev'700 in view of Viole et al. (US Patent 6,610,004, hereinafter Viole'004).

Regarding claim 11, Izraelev'700 discloses the invention substantially as claimed but does not expressly disclose that the blood pump further include a protective cage disposed over at least one of said blood inlets. In the same field of endeavor, Viole'004 teaches a housing with openings having a cage-like arrangement to shield the pump blades from damaging endothelial lining (column 8, lines 23-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Izraelev'700 with the cage structure of Viole'004 to provide Izraelev'700 with the same advantages of preventing damage to the endothelial lining.

9. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Izraelev'700.

Izraelev'700 discloses the invention substantially as claimed, but does not expressly disclose a subcutaneous rechargeable battery. However, it is well known in the art to use subcutaneous rechargeable batteries to power implanted devices so that the device may be used beyond a single battery lifetime without need for explant or

additional surgery which might further injure the patient or damage the implanted device. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system as taught by Izraelev'700 with a rechargeable subcutaneous battery to provide the advantage of being able to extend the usage of the implanted device without the need to perform surgery and explant the device, causing further damage to the device and the patient, as is well known in the art.

10. Claims 5 and 7 are rejected under 35 U.S.C. 102(e) as anticipated by Eistrup'602 or, in the alternative, under 35 U.S.C. 103(a) as obvious over Eistrup'602 in view of Viole'004 or in view of Jarvik (US Patent 4,994,078, hereinafter Jarvik'078).

Regarding claims 5 and 6, the cannula disclosed in Eistrup'602 is capable of extending across a valve or through an opening created in the aorta. Alternatively, in the same field of endeavor, Viole'004 teaches a cannula passing through the aorta so that blood may be directed from a first to a second blood vessel (column 16, lines 31-56). Similarly, Jarvik'078 teaches inserting a cannula into the aortic wall and across the aortic valve to make the valve incompetent and permit leaks in a suture line to be detected and repaired before connection of the intraventricular blood pump is made (column 14, lines 34-41). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Eistrup'602 with the cannula placed across a valve or the aorta to provide the Eistrup'602 system with the same advantages of directing blood across blood vessels or detecting and repairing suture leaks before a blood pump is connected permanently.

11. Claim 6 is rejected under 35 U.S.C. 102(e) as anticipated by Eistrup'602 or, in the alternative, under 35 U.S.C. 103(a) as obvious over Eistrup'602 in view of Zafirelis et al. (US Patent 6,808,508, hereinafter Zafirelis'508).

Regarding claim 6, Eistrup'602 discloses a cannula capable of being placed through an opening in the atrial septum. Alternatively, Zafirelis'508 teaches a transseptal cannula placed through the atrial septum for returning oxygenated blood to the arterial system of the patient (ABSTRACT). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Eistrup'602 with the transseptal cannula as taught by Zafirelis'508 in order to provide the Eistrup'602 system with the same advantage of returning oxygenated blood to the arterial system of a patient (motivation to combine provided by Zafirelis'508 ABSTRACT).

12. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eistrup'602 in view of Viole'004 et al.

Regarding claim 11, Eistrup'602 discloses the invention substantially as claimed but does not expressly disclose that the blood pump further include a protective cage disposed over at least one of said blood inlets. In the same field of endeavor, Viole'004 teaches a housing with openings having a cage-like arrangement to shield the pump blades from damaging endothelial lining (column 8, lines 23-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Eistrup'602 with the cage structure of Viole'004 to provide Izraelev'700 with the same advantages of preventing damage to the endothelial lining.

13. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Izraelev'700 in view of Jarvik (US 6,227,820, hereinafter Jarvik'820).

Regarding claims 19 and 20, Izraelev'700 is considered to disclose the invention substantially as claimed, but does not expressly disclose that the rotor magnets be placed in the rotor distal ends and that the casing magnets be placed in the blood inlets. In the same field of endeavor, Jarvik'820 teaches placement of magnets in each end of a rotor and permanent magnets at the inflow ends of the rotor in order to maximize separation from the magnetic bearing components at each end so that the magnetic forces of interaction between the motor and bearing are low (Figs. 8 & 9; column 6, lines 1-54). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system as taught by Izraelev'700 with the rotor end placement of magnets as taught by Jarvik'820 to provide Izraelev'700 with the same advantage of maximizing rotor and bearing separation while minimizing the magnetic forces of interaction.

14. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eistrup'602 in view of Jarvik (US 6,227,820, hereinafter Jarvik'820).

Regarding claims 19 and 20, Eistrup'602 is considered to disclose the invention substantially as claimed, but does not expressly disclose that the rotor magnets be placed in the rotor distal ends and that the casing magnets be placed in the blood inlets. In the same field of endeavor, Jarvik'820 teaches placement of magnets in each end of a rotor and permanent magnets at the inflow ends of the rotor in order to maximize separation from the magnetic bearing components at each end so that the magnetic

forces of interaction between the motor and bearing are low (Figs. 8 & 9; column 6, lines 1-54). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system as taught by Eistrup'602 with the rotor end placement of magnets as taught by Jarvik'820 to provide Eistrup'602 with the same advantage of maximizing rotor and bearing separation while minimizing the magnetic forces of interaction.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

26 March 2008

/George Manuel/
Primary Examiner